REMARKS

Regarding the withdrawn Rejections:

Applicants are pleased to note that the rejections of claims 1, 3 – 19 and 21 – 24 under 35 U.S.C. §112, second paragraph, as well as the rejection of claims 1, 3 – 19, 21 – 24 under 35 U.S.C. §102(b) have been withdrawn.

Regarding the new Restriction Requirement:

In response to applicants' traversal of the restriction requirement made in the previous Office action, the examiner made a nominal attempt to switch the grounds of the restriction requirement to the appropriate unity of invention standard, merely stating that "the invention lacks unity since claim 1 is known or suggested by the art."[1] Since, this is clearly a new ground for restriction, Applicants assert that the requirement was improperly made final.

At any rate, applicants traverse the newly raised restriction requirement. The examiner should reconsider the requirement for restriction. The appropriate legal standard regarding restriction is whether "[t]he international application … relate[s] to one invention only or to a group of inventions so linked as to form a single general inventive concept."[2] Furthermore, "[w]here a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."[3] It is respectfully submitted that the present invention properly relates to a single general inventive concept.

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[1] Page 2, lines 8 – 9 of the present Office action.
[2] PCT RULE 13.1.
[3] PCT RULE 13.2.

The oral dosage form with delayed release of active ingredient as claimed in claim 1 "define[s] a contribution which each of the claimed inventions, considered as a whole, makes over the prior art," [4] and therefore constitutes the "one or more of the same or corresponding special technical features," which are involved in the technical relationship between the embodiments of applicants' invention(s). Each embodiment of the claimed invention requires this oral dosage form with delayed release of active ingredient, thus the requirement of unity of invention referred to in Rule 13.1 is fulfilled. In other words, the present requirement for restriction is inappropriate under the proper "Unity of Invention" standard. The restriction requirement should be withdrawn.

If the examiner maintains the improper finality of the newly raised restriction requirement, applicants respectfully request that the issue of whether the examiner's requirement for restriction was proper be held in abeyance in accordance with 37 C.F.R. § 1.144, which states that "[a]fter a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal."[5]

Regarding the Rejection under 35 U.S.C. §103

Claims 1, 3 – 19, and 21 – 24 stand rejected under 35 U.S.C. §103(a) over Kolter et al. (US 6,066,334) in view of Ortega (US 4,837,032).

Kolter et al. is directed to instant release or quick release preparations, and no teaching, suggestion, motivation or apparent reason has been shown to modify Kolter et al. to arrive at the delayed release preparation of the present invention. Instead, the examiner has asserted that no patentable weight is given to the phrase "dosage form with delayed release," because the phrase is in the preamble to the claim. Despite the examiner's assertion, it is well-settled that "[t]he determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no

[4] PCT RULE 13.2.
[5] 37 C.F.R. § 1.144.

litmus test defining when a preamble limits the scope of a claim."[6] Moreover, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention...."[7]

A claim preamble should be given patentable weight, "[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim."[8] The preamble of claim 1, "An oral dosage form with delayed release of active ingredient ..." when read in the context of the entire claim clearly recites a limitation of the claim. The examiner has erred in cursorily characterizing this limitation as a "recitation of intended use," because "[t]he determination of whether preamble recitations are structural limitations or mere statements of purpose or use 'can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'"[9]

The examiner's proposed combination does not teach all of the claim limitations, because it does not teach an oral dosage form with delayed release of active ingredient. For this reason, the examiner has failed to establish a *prima facie* case of obviousness. "To establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations."[10] The present rejection is in error and should be withdrawn.

Moreover, since the Kolter et al. reference is directed to:

> [a] solid, rapid release, pharmaceutically active composition, from which the active ingredients are released within a time of from 0.1 to 1 hour, as measured in simulated gastric acid[,][11]

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[6] MPEP § 2111.02, citing Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002).
[7] Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d at 808-09, 62 USPQ2d at 1785.
[8] *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).
[9] MPEP § 2111.02, citing Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966.
[10] MPEP §2143.
[11] Claim 1 of US 6,066,334.

it should be clear that in order to start from the Kolter et al. reference and arrive at the present invention which is directed to:

> [a]n oral dosage form with delayed release ... comprising from 20 to 80% ... of a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone...wherein the ratio of polyvinyl acetate to polyvinylpyrrolidone is from 6:4 to 9:1 and said formulated mixture of polyvinyl acetate and polyvinylpyrrolidone facilitates said delayed release[,]

a change in the principle of operation of the Kolter et al. reference would be required. To start from the Kolter et al. reference and arrive at the present invention, a skilled artisan would need change the principle of operation of the Kolter et al. reference by changing from a rapid release composition to a dosage form with delayed release of active ingredient. It is well-settled that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious."[12] Thus, a *prima facie* case of obviousness has not been established, and it seems unlikely that a *prima facie* case of obviousness could be established using Kolter et al. as the primary reference.

Applicants note that the examiner has stated, "Kolter teaches a range of release times"[13] and that Ortega teaches "how to optimize the release profile."[14] The examiner's argument is not well-taken, because the release times mentioned by Kolter are all immediate release times within a very narrow range. Ortega provides no teaching, suggestion, motivation or apparent reason to change the principle of operation of the Kolter et al. reference by changing from a rapid release composition to a dosage form with delayed release of active ingredient.

Finally, the examiner is directed to page 3, lines 17 – 21 of the specification, which states:

> [t]he formulated mixture of polyvinyl acetate and

[12] MPEP §2143.01, citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)
[13] Page 4, line 5 of the present Office action.
[14] Page 4, line 6 of the present Office action.

> polyvinylpyrolidone is, because it is an intimate mixture of a lipophilic with a hydrophilic polymer, more suitable for release slowing than are the abovementioned substances. Combinations of this type are described in US patent 5,490,990.

By formulating PVP and PVAc together prior to admixing the formulated mixture with the other components an intimate mixture of the two copolymers is formed. Of course, the distinctive release patterns of the present invention are due to the formulation of the dosage forms plus the choice of amounts used in the overall mixture not only to the presence of the formulated mixture of polyvinyl acetate (PVAc) and polyvinylpyrrolidone (PVP).

In comparison, Ortega discloses granulating PVP and active ingredient in the presence of an organic solvent and subsequently mixing the dried granules with PVAc and a lubricant mixture. Neither Ortega nor Kolter et al. disclose a formulated mixture of PVP and PVAc as required by the present claims.

Thus, the examiner's argument that "Ortega specifically teaches changing the release rate or profile by altering the amount of binder[,]"[15] ignores an important feature of the claimed invention, i.e., the requirement of a formulated mixture of polyvinylacetate and polyvinylpyrrolidone. The examiner's argument also seems to demonstrate a misunderstanding of the claimed technology. As mentioned in the reply to the Office action of July 03, 2006, combining the disclosures of the Kolter et al. reference and the Ortega reference, and modifying the amount of a randomly chosen binder, does not result in a change of the principle of operation of the Kolter et al. reference so as to impart delayed release properties. Thus, even when combined, the references fail to teach or suggest all of the claim limitations. Again, "[t]o establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations."[16] The examiner has not established a *prima facie* case of obviousness. The present rejection is in error and should be withdrawn. Favorable action is solicited.

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[15] Page 4, lines 13 – 14 of the present Office action.
[16] MPEP §2143.